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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,088	08/20/2001	Roberto A. Gaxiola	883933.0067	7374

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/934,088

**Applicant(s)**

GAXIOLA, ROBERTO A.

**Examiner**

Ashwin Mehta

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on October 7, 2004 & June 29, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-48, 51, 54, 56-59, 66-70, 77-82 and 84-91 is/are pending in the application.
- 4a) Of the above claim(s) 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-45, 47, 48, 51, 54, 56-59, 66-70, 77-82 and 84-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants are reminded to cancel non-elected and withdrawn claim 46.
2. The objection to the specification regarding paragraph [0065] is withdrawn.
3. The objections to claims 40, 58, 71, and 73 are withdrawn in light of the claim amendments or cancellations.
4. The rejection of claims 35, 36, 53, 58-76, 59, 68, 69, 75, and 76 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the claim amendments or cancellations.
5. The provisional rejection of claims 38, 43, 44, 49, 51, 55, 56, 57, 77, and 78 under 35 U.S.C. 101 as claiming the same invention as that of claims of copending Application No. 09/834,998 is withdrawn.
6. The provisional rejection of claims 33-45, 47, 48, 51-57, 68, 69, and 75-79 under 35 U.S.C. 101 as claiming the same invention as that of claims of copending Application No. 10/344,658 ('658) is withdrawn.

### ***Claim Objections***

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7. Claim 33 and 79 are objected to because of the following informalities:

In claim 33: the recitation, "driven pump" in line 3 appears to be a typographical error and should be removed.

In claim 79: the recitation, "expression" in line 4 appears to be a typographical error and should be removed.

Appropriate correction is required.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 84 and 86 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 82 and 83 of copending Application No. 09/834,998 ('998). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claims 84 and 86 are directed to a transgenic plant having incorporated in its genome a chimeric vacuolar pyrophosphatase (VPP) gene operably linked to a CaMV 35S double tandem enhancer that causes overexpression of said gene in said plant, or wherein the VPP gene is a plant or yeast gene. Claims 82 and 83 of '998 are directed to the same subject matter and are co-extensive in scope with instant claims 84 and 86.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 33-45, 47, 48, 51, 54, 56, 57, 59, 68, 69, 77-79, 85, 87-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 82-85 of U.S. Patent No. 09/834,998. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same subject matter. Claims 82-85 of '998 are directed to a transgenic plant having incorporated in its genome a chimeric vacuolar pyrophosphatase (VPP) gene operably linked to a CaMV 35S double tandem enhancer that causes overexpression of said gene in said plant; or wherein the VPP gene is a plant or yeast gene; or wherein the VPP is AVP1, or progeny or seed harboring the chimeric VPP gene. Instant claim 33 encompasses a transgenic plant comprising an exogenous tonoplast pyrophosphatase driven H<sup>+</sup> gene operably linked to regulatory element(s) that result in upregulated expression of vacuolar pyrophosphatase. The instant specification discloses that the AVP1 gene is a tonoplast pyrophosphatase driven H<sup>+</sup> pump gene (for example, paragraph 0019). It is obvious that claim 33 encompasses plants that are encompassed by claim 82 of '998.

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Claims 38-45, 78, 82, and 87 limit the exogenous gene to be the AVP1 gene. Claim 43 limits the regulatory element to comprise a double tandem enhancer of the 35S CaMV promoter. The properties of the plants, seed and progeny of the instant claims are inherent to the claimed plants, progeny and seed of the co-pending application, as they express the same exogenous gene. The plant cells of instant claims 51, 54, 56, and 57 can obviously be found in the claimed plants and seeds of '998.

10. Claims 33-45, 47, 48, 51, 54, 56, 57, 68, 69, 77-79 remain and claims 59, 84-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 28, 42, 48, 61, and 74 of copending Application No.

10/344,658, for the reasons of record stated in the Office action mailed September 24, 2003.

11. In the paper submitted June 29, 2004, Applicant indicated that the Applicant and assignee are in the process of assessing ownership and inventorship of the instant application and co-pending application 09/834,998 (page 5, 4<sup>th</sup> full paragraph). The double patenting rejections are maintained.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 44, 45, 47, and 48 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention, for the reasons of record stated in the Office action mailed September 24, 2003. Applicant traverses in the paper filed June 29, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Regarding claim 45: the claim was found indefinite because it was not clear it differed from claim 44, which both depend from the same claim and introduce the same limitation, excepting that claim 45 indicates that the AVP1 gene or homolog thereof is derived from a transgenic plant. The metes and bounds of the claim were unclear. Both claims have been amended to be dependent on claim 40. However, it remains unclear how claim 44 differs from claim 45. It is unclear how the recitation, "derived from a transgenic plant" limits claim 45.

Regarding claims 47 and 48: the claims were found indefinite because it is not clear if the seed and progeny comprise the exogenous gene. Applicant indicated that the claims were amended to address the examiner's concerns (response, page 5, last paragraph). However, claims 47 and 48 were not amended.

13. Claims 33-37, 39-45, 51, 54, 56-59, 66-70, 77-82, 84-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 33, 51, and 77: in claim 33, the recitation, "tonoplast pyrophosphatase driven H<sup>+</sup> pump gene" renders the claim indefinite. It is not clear that the gene encodes the vacuolar pyrophosphatase mentioned at the end of the claim. It is suggested that the recitation, --, encoding a vacuolar pyrophosphatase,-- be inserted in line 3 after "gene", and the recitation,

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“said” be inserted in line 4 before “vacuolar”. Claims 51 and 77 are indefinite for the same reason, and it is suggested that they be amended in the same manner as claim 33.

In claim 39: there is insufficient antecedent basis for the limitation, “the AVP1, or homolog thereof” in the claim or parent claim 33.

In claims 56 and 57: there is insufficient antecedent basis for the limitation, “the AVP1” in the claim or the claim from which it depends.

In claim 59: the recitation, “the counterpart wild type plant” renders the claim indefinite. It is not clear what is encompassed by “counterpart.” It is suggested that the recitation be replaced with, --an untransformed plant of the same species--.

In claim 80: the recitation, compared with retention of solute species in a wild-type plant vacuole” renders the claim indefinite. It is not exactly clear if the plant is same species as the plant into which the tonoplast pyrophosphate driven H<sup>+</sup> pump gene was introduced. It is suggested that the recitation be replaced with, --vacuoles of a non-transgenic plant of the same species that does not comprise said tonoplast pyrophosphate driven H<sup>+</sup> pump gene.

In claims 84 and 89: the recitation, “35S (CaMV) promoter double tandem enhancer gene” renders the claim indefinite. It is unclear what the recitation is referring to. It is suggested that the recitation be replaced with, --double tandem enhancer of the CaMV 35S promoter--, if that is what is intended.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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14. Claims 87 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn towards a transgenic plant having incorporated in its genome a chimeric vacuolar pyrophosphatase (VVP) gene, wherein the VPP is AVP1 or AVP2, operably linked to a 35S (CaMV) promoter double tandem enhancer gene.

The specification does not provide written descriptive support for "AVP2". There is no mention of AVP2 at all in the specification, and this recitation must be removed from the claim. This is a NEW MATTER rejection.

15. Claims 33-45, 47, 48, 51, 54 remain and 56-58, 66, 68-70, 77-82, and 84-91 are, rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic plants overexpressing AVP1 and having increased tolerance to water deficit and increased NaCl concentrations, does not reasonably provide enablement for transgenic plants having resistance to chilling temperatures, or for increasing the level of expression of vacuolar pyrophosphatase other than by transgenically expressing AVP1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection modifies the scope of enablement rejection presented in the Office action mailed September 24, 2003. Applicant traverses the rejection in the paper filed June 29, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Applicant's response does not address the issue that the specification does not enable an increase in chilling or freezing tolerance of transgenic plants expressing AVP1.

Regarding the issue that the specification does not enable regulating vacuolar pyrophosphatase expression in plants other than by transgenic expression AVP1: claim 40 broadly indicates that expression of AVP1 homolog can result in overexpression of AVP1. However, neither the specification nor the prior art teach any AVP1 homolog that has the ability to cause overexpression of AVP1 (another product). In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how AVP1 gene expression can be increased, by transgenic expression of a homologous gene.

The specification does not enable the claimed transgenic plants transformed with genes other than AVP1. Applicants argue that the universality of this gene in the plant world, its highly conserved nature, the transgenic tobacco and Arabidopsis plants, provide ample support for the claims (response, page 4<sup>th</sup> full paragraph). Applicant provides in Exhibit A results of a BLAST search of the AVP1 gene, and a table summarizing the results in Exhibit C. Applicant provides Baltcheffsky et al. in Exhibit B, arguing that it shows the similarity of protein pumping plant enzymes (response, page 6, 4<sup>th</sup>-6<sup>th</sup> full paragraphs). However, not all vacuolar pyrophosphatases have the same functions. Drozdowicz et al. (Plant Physiol., 2000, Vol. 123, pages 353-362) teach that AVP2 is functionally divergent from AVP1 (pages 356-357). It is therefore unclear that all AVP1 homologs can be used to make the claimed transgenic plants or be used in the claimed methods, to confer the same properties on transgenic plants as does transgenic expression of AVP1. Given the breadth of the claims, unpredictability of the art and

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lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 33-45, 47, 48, 51, 54, 56, 57, 68, 69, 77-79 remain and claims 59, 84-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaxiola et al. (U. S. Publication No. 2002/0178464 A1), for the reasons of record stated in the Office action mailed September 24, 2003. Applicant traverses the rejection in the paper filed June 29, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that the reference can only be used as of the date of publication, unless it issues as a patent (response, page 7, 2<sup>nd</sup> full paragraph). However, this is incorrect. The 102e date of the reference is November 10, 1999.

17. Claims 33-45, 47, 48, 51, 54, 56-59, 66-70, 77-82, and 84-91 are rejected, and non-elected claim 46 is withdrawn.

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***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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December 16, 2004



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